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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/426,545 10/23/99 ROBBINS D DEX-0054

JANE MASSEY LICATA
66 E MAIN STREET
MARTON NJ 08053

HM12/0212

EXAMINER

WOITACH, J

ART UNIT	PAPER NUMBER
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1632

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DATE MAILED: 02/12/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/426,548

Applicant(s)

ROBBINS ET AL.

Examiner

Joseph Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Applicants amendment filed November 15, 2000 (paper number 10) has been received and entered. Claims 4-8 have been canceled. Claim 1 has been amended. Claims 1-3 are pending and currently under examination.

Claim Objections

The objection to claim 1 is withdrawn. Applicants argue that the claim does not encompass a specific SEQ ID NO, rather a specific mutation of the gene sequence of hMLH1 and hMSH2 as defined in the specification on pages 15-17, and does not have to recite a specific SEQ ID NO. Examiner acknowledges this distinction and withdraws the objection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 8 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn. Applicants have canceled claim 8 rendering the basis of this rejection moot.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

Claim 8 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is withdrawn.

Applicants have canceled claim 8 rendering the basis of this rejection moot.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically:

Claim 1 is unclear and indefinite with respect to the specific nucleotide sequences of the mutations cited.

Applicants argue that the definiteness of a claim should be analyzed A) in light of the disclosure; B) the teachings in the prior art; and C) claim interpretation given by one possessing the ordinary skill in the pertinent art at the time of the invention was made (MPEP 2173.02).

Applicants argue that hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2 and hMSH2 mutant 3 are defined in the specification and what is meant by the recitation of these terms when read in light of the specification would be clear to one of skill in the art. Applicants arguments have been fully considered but not found persuasive.

Examiner agrees that the specific mutations are clearly defined and one of ordinary skill in the art would know what these specific mutations are, however claim 1 recites 'a variant MLH1 or MSH2 gene comprising' which is open language reading on the whole gene sequence. The specification clearly defines the polynucleotide base pair mutations, however it fails to adequately define the elements which are encompassed by a variant MLH1 or MSH2 gene, and therefore the claim is not clear and indefinite since one of ordinary skill in the art would not know the metes and bounds of what is encompassed by a MLH1 or MSH2 gene.

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Claims 2 and 3 are unclear and incomplete in the recitation of 'the presence of the variant gene is indicative of a susceptibility to hereditary non-polyposis colorectal cancer'. Applicants argue that no additional method steps are necessary to indicate the a predisposition to colorectal cancer since the claim is dependent on claim 1. Applicants arguments have been fully considered but not found persuasive.

As claim 2 and 3 are written, they require only screening of the DNA sample since after screening, the presence or absence of the specific mutations encompassed by claim are detected. It is unclear if what is also encompassed is wherein the absence of the variant is indicative of colorectal cancer. Examiner does agree that the claim is complete in method steps, however when read in light of the specification, one must screen the DNA sample for the presence of the variant MLH1 or MSH2 gene of claim 1, wherein the presence of the variant gene is indicative of colorectal cancer.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3 rejected under 35 U.S.C. 102(a) as being anticipated by Farrington *et al.* is withdrawn.

The declaration by Juili Lin-Goerke filed with this amendment states that the authors listed on the cited reference of Farrington *et al.*, but not on the instant application, aided in obtaining the data disclosed in the reference and did not contribute to the actual invention disclosed and claimed. The declaration is found persuasive and obviates use of the reference because it is not known or used by another. Therefore, the rejection is withdrawn.

Claims 2-3 stand rejected under 35 U.S.C. 102(b) as being anticipated by Weber *et al.*

Claim 1 has been amended to delete [hMLH mutant 2] which was anticipated by cited reference. With respect to the remaining mutations, Applicants argue that Weber *et al.* do not specifically teach hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2 and hMSH2 mutant 3 and thus claims 2 and 3 cannot be anticipated since these mutations are not taught. Applicants arguments have been fully considered but not found persuasive.

As discussed above in the 112, second paragraph rejections, claims 2 and 3 encompass the method of screening the DNA sample, however since ~~the~~ the screening does not involve specifically

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screening for a specific mutation, the presense or the absence of a mutation is indicative of the screening method. Weber *et al.* teach a method and the appropriate primers to do genomic sequencing of MLH1 and MSH2, and detect mutations predictive of heredity nonpolyposis colorectal cancer (whole document, particularly Table 1 and 2). Therefore, the claim is anticiapted by Weber *et al.*

Claims 2-3 stand rejected under 35 U.S.C. 102(e) as being anticipated by Liskay *et al.*

Claim 1 has been amended to delete [hMLH mutant 2] which was anticipated by cited reference. With respect to the remaining mutations, Applicants argue that Liskay *et al.* do not specifically teach hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2 and hMSH2 mutant 3 and thus claims 2 and 3 cannot be anticipated since these mutations are not taught. Applicants arguments have been fully considered but not found persuasive.

As discussed above, claims 2 and 3 encompass the method of screening the DNA sample, however since a the screening does not involve specifically screening for a specific mutation, the presense or the absence of a mutation is indicative of the screening method. Liskay *et al.* teach a method and the appropriate primers for the detection of mutations in MLH1 and MSH2 which are associated and predictive of heredity nonpolyposis colorectal cancer (whole document and in particular figure 1, and sequences of figures 2-5, 13-16). Therefore, the claim is anticiapted by Liskay *et al.*

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Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach, whose telephone number is (703) 305-3732. The examiner can normally be reached on Monday through Friday from 8:00 to 4:30 (Eastern time).

If attempts to reach the examine by telephone are unsuccessful, the examiner's supervisor, Karen M. Hauda, can be reached on (703) 305-6608. The fax number for group 1600 is (703)308-4724.

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An inquiry of a general nature or relating to the status of the application should be directed to Kay Pickney whose telephone number is (703) 305-3553.

Joseph T. Voitach

Karen M. Hauda
KAREN M. HAUDA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600